In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-0804V UNPUBLISHED

MICHAEL THOMAS.

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 23, 2021

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Ronalda Kosh, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On May 31, 2019, Michael Thomas filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that he suffered a right shoulder injury related to vaccine administration (SIRVA) as a result of an influenza ("flu") vaccine received on September 16, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find there is preponderant evidence to establish the vaccination alleged as causal in this case was administered to Petitioner's right deltoid, as he has alleged.

I. Relevant Procedural History

On November 3, 2020, Respondent filed his Rule 4(c) Report asserting that Petitioner had not established by a preponderance of the evidence that he suffered a Table injury, and therefore was not entitled to a presumption of vaccine causation. ECF 28. Specifically, Respondent argued that "[t]he contemporaneous vaccine administration record clearly reflects that [P]etitioner's September 16, 2018 flu vaccine was administered into [P]etitioner's left deltoid, not his right shoulder as alleged." *Id.* at 8 (emphasis in original).

After a status conference, Petitioner was provided with the opportunity to submit any additional evidence related to the site of vaccination, and he filed an affidavit from Mr. Kenneth Newnes, a friend. After reviewing this record, Respondent indicated that he would continue to defend the case. ECF 31. Petitioner then requested that he be allowed the opportunity to file a motion for ruling on the record, and he did so on July 6, 2021. ECF 33. Respondent filed his response on August 6, 2021, and Petitioner filed his reply on August 19, 2021. ECF 34; ECF 35. Therefore, this matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in his right arm. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

In fact, the United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that the contents of medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I have conducted a complete review of the record, including all medical records, affidavits, Respondent's Rule 4 report, and additional evidence filed. I make the following findings of fact:

- Petitioner received a flu vaccine at a CVS pharmacy on September 16, 2018. Ex 1.
- The Vaccine Administration Record (VAR) pertaining to this vaccination is computer-generated, and includes a preprinted vaccine lot number, manufacturer, and expiration date. Ex 1 at 2. The site of vaccination is listed as "Left Deltoid." *Id*. The VAR includes a handwritten signature and date from Petitioner and the handwritten signature of the vaccine administrator. *Id*.
- On October 1, 2018, Petitioner presented to East Bay Medical Center for an "immediate care" visit. Ex 2 at 7. He reported progressive *right* shoulder pain after receiving the flu shot. *Id*. Petitioner stated that the "shot was given very high," physically pointing to the subacromial region of his right shoulder. *Id*. Examination of the right upper extremity revealed a "wellcircumscribed 3 cm" area of swelling with tenderness "anterior to [the] subacromial region," tenderness in the subacromial and acromioclavicular region of the right shoulder, and right shoulder abduction limited to 30 degrees. *Id*.
- An MRI of Petitioner's right shoulder performed on October 24, 2018, revealed "marked sprain or partial-thickness tear of the distal supraspinatus tendon," subacromial and subdeltoid bursitis, and tear of the superior labrum. Ex 2 at 55.
- On October 25, 2018, Petitioner presented for an orthopedic consultation with Dr. Philip Christ, at which time he reported that he began experiencing decreased range of motion and severe pain in his right shoulder after receiving the flu shot at CVS. Ex 2 at 51. During the appointment, Petitioner physically indicated (by pointing) that he received the injection in the right deltoid area. *Id.* at 52.

- On November 16, 2018, Petitioner presented to Next Step Physical Therapy for an intake evaluation. Ex 3 at 55. Petitioner reported "development of right shoulder pain" following an "excessively proximal flu injection." *Id*.
- Dr. Mark Ritch, a neurologist, evaluated Petitioner on January 24, 2019. Ex 4 at 6. During the appointment, Petitioner reported pain developing after a flu shot "in the right deltoid muscle" on September 16, 2018. *Id.* Dr. Ritch's assessment included "[r]ight deltoid pain and weakness after a flu shot." *Id.*
- At four subsequent appointments with Dr. Christ in 2019, Petitioner reiterated that his right shoulder pain "began after a flu shot." Ex 2 at 40, 42; Ex 9 at 1, 3.
- In his affidavit, Petitioner averred that he received the flu shot in his right shoulder, which caused "excruciating pain and limited movement of [his] right shoulder and arm." Ex 8 at ¶ 1.
- Petitioner submitted an affidavit from Kenneth Newnes, who accompanied Petitioner to the pharmacy on the day he received his flu shot. Ex 10. Mr. Newnes states that he received the flu shot prior to Petitioner and that he sat in a chair where his left shoulder "was up against the wall while the pharmacist administered the shot in my right shoulder." Id. at ¶ 1. Mr. Newnes also avers that Petitioner sat in the same position when he received his flu shot and that he (Mr. Newnes) watched the pharmacist administer the vaccine in Petitioner's right shoulder. Id. Mr. Newnes further asserts that Petitioner began complaining of right shoulder pain later that day and continued to complain of right shoulder pain and difficulty lifting his right arm "the next day . . . [and] every day . . . for a few weeks." Id. at ¶¶ 2-3.

As discussed in other decisions, consistent reporting to treating physicians that a shoulder injury was associated with a specific vaccination in the same shoulder can serve as probative evidence that can overcome a contradictory vaccine administration form. See e.g., Desai v. Sec'y of Health & Human Servs., No. 14-811V, 2020 WL 4919777, at *13-14 (Fed. Cl. Spec. Mstr. July 30, 2020); Mogavero v. Sec'y of Health & Human Servs., No. 18-1197V, 2020 WL 4198762 (Fed. Cl. Spec. Mstr. May 12, 2020); Hanna v. Sec'y of Health & Human Servs., No. 18-1455V, 2021 WL 3486248 (Fed. Cl. Spec. Mster. July 15, 2021); Mezzacapo v. Sec'y of Health & Human Servs., No. 18-1977V, 2021 WL 1940435, at *7 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

In addition, it appears the VAR in this case contains computer generated information. As observed in other SIRVA cases, it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect. See, e.g., Desai, 2020 WL 4919777, at *14; Rodgers, 2020 WL 1870268, at *5; Stoliker v. Sec'y of Health & Human Servs., No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018); see also Mezzacapo, 2021 WL 1940435, at *6 ([t]his is an issue that arises repeatedly in the specific context of . . . SIRVA claims [because] pharmacy vaccine administration records are not necessarily reliable in documenting [the] injection site"). Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply because they come first – and in fact the nature of their creation provides some basis for not accepting them at face value, absent persuasive evidence that they reflect a treater's agency in identifying situs.

In this case, Petitioner consistently reported right shoulder pain which he attributed to his September 2018 vaccination. He also provided this information during his "immediate care" visit within two weeks of vaccination and on multiple occasions to various medical personnel over the next year.³ And Petitioner's subsequent statements to his treatment providers are further consistent with those made in his petition and sworn affidavit.

The only contrary evidence is the immediate vaccination confirmation record – the VAR – which indicates a left arm vaccination. Respondent argues that the VAR's contemporaneous quality is grounds to give it substantially more weight than other subsequent evidence. ECF 34. However, as discussed above, *all* treatment records in this case contain information regarding examinations and observations of Petitioner's right arm/shoulder. Further, these records universally describe a right shoulder injury. The medical records, combined with the affidavits of Petitioner and Mr. Newnes,⁴ provide good reason for discounting the reliability of the notation regarding situs on the VAR.

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³ In cases where I have determined that a petitioner provided sufficient evidence to rebut the site of administration listed in the vaccine record, the medical records demonstrated consistent and multiple reports of pain attributed to the vaccination alleged as being administered in the injured shoulder, along with efforts to obtain treatment close in time to vaccination. See, e.g., Gallo v. Sec'y of Health & Human Servs., No. 18-1298V, 2019 WL 7496617, at *3-4 (Fed. Cl. Spec. Mstr. Dec. 5, 2019); Rodgers v. Sec'y of Health & Human Servs., No. 18-0559V, 2020 WL 1870268, at *3-4 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); cf. Marion v. Sec'y of Health & Human Servs., No. 19-0495V, 2020 WL 7054414, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2020) (Petitioner failed to rebut the site of administration listed on the vaccine record when he did not complain of pain in the allegedly injured shoulder until more than six months after vaccination, did not attribute his shoulder pain to the vaccine until an additional three months thereafter, and sought medical treatment for other conditions during the first six months after vaccination without mention of shoulder pain).

⁴ Respondent contends that Mr. Newnes's affidavit should be afforded little weight because it was prepared years after the date of vaccination and for the purpose of litigation. ECF 34. However, the Federal Circuit recently held that while a lay witness may not be competent to testify as to causation or medical diagnosis,

Accordingly, I find there is preponderant evidence to establish the vaccination alleged as causal in this case was administered to Petitioner in the right deltoid on September 16, 2018.

V. Scheduling Order

Given my finding of fact regarding the site of Petitioner's vaccination, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Respondent shall file a status report regarding his current position by no later than Monday, October 25, 2021.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[&]quot;the same is not true for sworn testimony as to facts within the witness's personal knowledge, such as the receipt of a vaccine and the timing and severity of symptoms." *James-Cornelius v. Sec'y of Health & Human Servs.*, 984 F.3d 1374, 1380 (Fed. Cir. 2021). Mr. Newnes accompanied Petitioner when he received his vaccine; therefore, he clearly had personal knowledge of the events of that day. While Mr. Newnes's affidavit, standing alone, might not serve as preponderant evidence to support a finding of situs, it closely aligns with the treatment records and Petitioner's affidavit, and further supports a finding that the flu vaccine was administered in Petitioner's right arm.